

REMARKS

Upon entry of the present amendment, claims 1-29 are pending in the above-referenced patent application and are currently under examination. Claim 1 has been amended. Claims 8-11, 13, 14, 19 and 21-28 have been withdrawn. Reconsideration of the application is respectfully requested.

Claim 1 has been amended to provide clarification. These amendments find support in the original claims as filed, as well as Figure 1. Additional support can be found throughout the specification.

Applicants believe the claim amendments add no new matter to the claims.

Applicants thank the Examiner for their time and comments during the Examiner Interview on October 3, 2007. Applicants discussed with the Examiner the Lebl reference, and agreement was reached that Lebl does not teach or disclose simultaneous reaction of the scaffold functional group and coding functional group with the reactive component. In responding to the instant Office Action, Applicants have amended the claims to more clearly set forth this distinction over Lebl.

The claims are rejected in various combinations under 35 U.S.C. §§ 112, 1st paragraph, 112, 2d paragraph and 102(b). Each of these rejections is addressed below in the order set forth by the Examiner.

I. REJECTION UNDER 35 U.S.C. § 112, 1st, WRITTEN DESCRIPTION

Claims 1-7, 12, 15-18, 20 and 29 have been rejected under 35 USC § 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants respectfully traverse the rejection.

The test for written description is whether the specification describes “the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.” See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116-17. “The subject matter of the claim need not be

described literally (i.e., using the same terms or in *haec verba*) in order for the disclosure to satisfy the description requirement.” (MPEP §§ 2163, 2163.02).

The Examiner alleges that the claim terms, such as “library of compounds,” “compound,” “synthesis template,” “scaffold functional group,” “reactive component,” “linkers,” etc., are broadly defined so as to encompass almost any chemical entity. The Examiner notes that the only examples provided are “peptides” or amino acids as the synthesized testing compounds, and peptides as the coding compounds, as well as certain small organic molecules as the testing compounds” and that “these examples do not provide representative number of species to indicate possession of the entire genus of methods of making any compound using any reactants.” The Examiner further states that amending the claims to using only amino acids as building blocks would not remove the unpredictability for generating any peptide using any amino acid and any coding building blocks.

This position is, however, inconsistent with the PTO policy, as patents are regularly issued with claims directed to methods of making using components not described based on their structural characteristics at all. Below, Applicants present an analysis of the law regarding the requirement for these claims having non-structural limitations. Since method claim 1 complies with the criteria of an allowable claim with non-structural limitations, this claim and its dependent claims are allowable.

The following analysis is divided into two parts. The analysis begins with an overview of the relevant law, which is followed by a fact analysis of pending claim 1 in view of the applicable law.

A. The Applicable Law: Where Compositions are Not at the Point of Novelty, Functional Language is Permitted

A review of the case law reveals that there are situations where an applicant can properly obtain claims directed to methods based on the use of a chemical compound that is defined solely by its function and not structure. Generally, these claims must pass several legal tests. First, the point of novelty of the claims should not reside in the compounds themselves, but rather in the discovery that their common function has the stated use. Second, there should be a routine assay that allows those of skill in the art to identify other compounds that are

suitable for use in the invention. Finally, there is usually a variety of compounds that can be used in the invention.

1. Where Compositions are Not at the Point of Novelty, Functional Language is Permitted

For a transformation method claim, the use of functional language to describe components attached to functional groups undergoing the transformation is proper when the functional language is not used at the “very point of novelty.” The Board of Appeals has provided a concise summary of this law in *Ex parte Barrick*, 84 USPQ 142 (Bd. Pat. App. & Int. 1949). The *Barrick* case is particularly useful because the Board had before it both a proper use of functional language and an improper use of functional language. In *Barrick*, a first set of rejected claims was directed to a process for preparing monomeric fluorine compounds, and the inventive step involved the use of a “polymerization inhibitor” in combination with a structurally defined composition. A second set of rejected claims recited “nonpolymerizing conditions” instead of a “polymerization inhibitor.” With respect to the first set of rejected claims, the Board held that the use of a “polymerization inhibitor” was acceptable because polymerization inhibitors were known and because their use in the reaction was the point of novelty -- not the compounds themselves. In finding this use of functional language acceptable, the Board cited with approval previous cases in which the use of terms such as “crystallization retarding agent,” “active decolorization agent,” and “nondeliquescent dispersing agent” were permitted in the claims. *Barrick* at 145.

The Board agreed with the Examiner, however, with respect to the use of “nonpolymerizing conditions” in the second set of rejected claims. In these claims, the Board found that the functional language was so broad that it read on prior art, which was not an issue for the first set of claims. In finding the use of functional language in the second set of claims unacceptable, the Board stated that “[t]his claim, therefore, fails to patentably distinguish over the French patent because it is **functional at the very point of novelty**” (emphasis added). *Barrick* at 145-146.

In addition, the use of functional language to define the elements of a claim at noncritical aspects of the claims dates back to early Supreme Court decisions. A good review of

the law can be found in *Application of Fuetterer*, 138 USPQ 217 (CCPA 1963). In *Fuetterer*, the Applicant had discovered that the addition of a protein with an inorganic salt to the materials used to make tire tread increased the stopping ability of tires made from the materials. Although the claim at issue is long, the relevant language is as follows:

A rubber stock for producing tire treads including ... a sufficient amount of a vulcanizing agent to vulcanize rubber, and a reinforcing agent ... said rubber stock also including a mixture of ... protein and a carbohydrate ... and **an inorganic salt that is capable of holding a mixture of said carbohydrate and protein in colloidal suspension** . . . in an amount sufficient to hold the mixture ... in a film of water ... when the [tire] tread rotatably engages a wet or icy road....

Fuetterer at 219 (Emphasis added). The bolded language, reciting the inorganic salt, was the basis for the Examiner's rejection. In considering the claim, the Board had no issue with the use of functional language for the vulcanizing rubber and reinforcing agents. However, the Board decided that the point of novelty was in the use of the salts and demanded more than a functional limitation at this point. The CCPA reversed finding that the Board and the Examiner had misidentified the point of novelty.

In the discussion, the *Fuetterer* court affirmed the older law of *Barrick* and clarified a subtle, but important point when defining the point of novelty in a claim. From the *Fuetterer* decision, when a claim has multiple elements, functional language can properly be used to define an element, so long as the element does not define the invention's ultimate function. In correcting the Board, the CCPA stated that the point of novelty was not "in the result obtained from the salts [colloidal suspension]". Rather, the court stated "appellant's exact point of novelty is a new combination of substances constituting a rubber tire tread stock."

Fuetterer at 221.

A more recent example of this concept is exemplified by *In re Herschler*, 200 USPQ 711 (CCPA 1979). In that case, the claimed invention was the use of DMSO to enhance delivery of physiologically active steroids, and the specification provided one example demonstrating the efficacy of the claimed methods. The PTO rejected the claims, in part, on the ground of lack of written description for not disclosing a representative number of physiologically active steroids. The CCPA reversed the PTO's rejection, reasoning that, because

the point of novelty was not the compositions of steroidal agents but a method of delivering the agents in combination with DMSO, explicit written disclosure of all steroidal agents was not required to meet the written description requirement. Therefore, *the written description requirement does not require all species of every claim term to be disclosed*; rather, only an adequate description of the claimed invention.

The final case is *In re Lange*, 209 USPQ 288 (CCPA, 1981). In *Lange*, the invention related to the use of electronegative gases to coat electrical devices to dampen arcing (sparks). The Examiner noted that the claims were broad enough to read on casting of electrodes and that the disclosure was limited to coating of preexisting electrodes. Convinced that this single species was not easily obtainable, the Examiner refused to allow the claims due to over breadth.

In rejecting the position of the Patent Office, the CCPA noted that the invention is the use of the gases to dampen sparks. No claim was drawn to casted electrodes. The entire claims were allowed and the CCPA stated:

However, although appellant can be required to limit his claims to that subject area which is adequately disclosed, **the existence of species which are not adequately disclosed does not require that the entire application be found nonenabling**. See *In re Cook*, 58 CCPA 1049, 439, F.2d 730, 169 USPQ 298 (1971). This is especially true in this case where, as stated by appellant at oral argument, the method of forming the electrodes is **not the inventive principle** [Emphasis added].

Applicants provide below two recent examples of issued claims drawn to a library of compounds where the examiner found the absence of chemical specificity in a claim satisfied the requirements under 35 U.S.C. § 112. U.S. Patent No. 5,840,485 (Lebl *et al.*):

1. A library for identifying and analyzing a ligand of an acceptor of interest comprising: a multiplicity of separate solid phase supports having a plurality of reactive functional groups; to each of which said supports are attached via said functional groups:
 - a) a species of test compound, said test compound comprised of a sequence of subunits; and
 - b) one or more species of coding molecule, wherein the coding molecules that are attached to each support:

- i) are comprised of α -amino acids, and
- ii) are topologically segregated from the test compound that is attached to each said support, such that the coding molecule is in the interior of each said support, and the test compound is attached to greater than 90% of the reactive functional groups on the exterior of each said support;

wherein, on each said support:

each species of coding molecule is different from the species of test compound;
and
the sequence of the subunits of the test compound is encoded by the species of coding molecules.

U.S. Patent No. 6,090,912:

1. A library for identifying a ligand or an acceptor of interest, the library comprising a multiplicity of separate solid phase supports, the surface of each support having attached a linker comprising a single species of test compound having a sequence of subunits, and the interior of each support having attached a coding molecule which encodes the sequence of subunits of the test compound, the linker having a bond that is cleavable by an enzyme that does not cleave a bond of the coding molecule.

Applicants request that deference be given to the prior examiner, who found the general language was adequately described pursuant to §112. For the law relied upon by the present Examiner is misapplied to the invention at hand. This is because the claims of this invention are not directed to the polypeptides and nucleic acids as compositions per se; but, to the formation of conjugates in a novel and patentable invention.

2. It Is Routine to Determine If a Compound Can Be Used in the Claimed Method

The second criterion for a proper claim including non-structural limitations is that one of skill in the art must be able to identify other compounds that can be used in the claimed method without undue experimentation. In some situations, the classes of the useful compounds are so well known that an identification test might not even be required. For instance, in *Herschler*, in granting the applicant the priority date of its foreign parent application, the CCPA voiced its opinion that the class of steroids is so well known that a single example supported the later claim to the entire group without assay or limitation.

On the other hand, when compounds useful for the claimed method are not as well known, a functional assay described in the specification will satisfy the requirement. In *In re Goffe*, 191 USPQ 429 (CCPA 1976), the claimed invention was a method of imaging and the first step of the appealed claim involved the use of a “nongaseous agglomerable layer.” The PTO argued that this functional language included many nonworking embodiments. The CCPA reversed the PTO’s decision and explained that undue experimentation would not be required because *Goffe*’s specification contained multiple working examples and a clear teaching of how to identify substitutes. In reversing the PTO’s decision, the CCPA stated:

For all practical purposes, the board would limit appellant to claims involving the specific materials disclosed in the examples, so that a competitor seeking to avoid the claims would merely have to follow the disclosure in the subsequently issued patent to find a substitute. However, to provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for preferred materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts...

Goffe at 431.

Similarly, *Application of Angstadt*, 190 USPQ 214 (CCPA 1976), provides further approval that assays described in the specification can be used to enable method claims involving the use of compounds beyond the compounds identified in the specification. In *Angstadt*, the invention was the catalysis of alkylaromatic hydrocarbon oxidation to form hydroperoxides. The catalyst was described in the claims as a hexaalkylphosphoramide and transition metal salt. The PTO argued that the catalyst was unpatentably broad because it was virtually undefined by structure, and the applicants had admitted that the claims read on inoperative catalysts. The CCPA acknowledged the PTO’s concerns about scope and inoperable embodiments. However, the CCPA reversed the PTO’s decision because the specification provided multiple examples of operable catalysts and, in addition, adequate teachings were provided regarding how one would make the catalysts and screen them for their ability to function as catalysts in the claimed methods. The issue in *Angstadt* was simply “undue experimentation.” In addressing this issue, the CCPA clearly explained that the PTO had the initial burden of establishing that the amount of

necessary experimentation was undue given the teachings of the specification. The CCPA further indicated that it was not applicants' burden to respond merely because the PTO expresses an unsupported opinion regarding the amount of effort that might be required to obtain catalysts beyond those described in the specification.

Finally, in *In re Johnson and Farnham*, 194 USPQ 187 (CCPA 1977), the PTO rejected a composition for a polymer, wherein the monomer comprised a subcomponent that was partially defined by a sigma value "sufficient to activate a halogen atom." In support of this rejection, the PTO indicated that an objective numerical value for the sigma value was required. In finding that functional language was sufficient, the CCPA stated:

The specification adequately details which sigma values are sufficient to carry out the reaction ...It is clear that those skilled in the art would have no trouble ascertaining whether any particular polymer falls within the scope of the claim.

Johnson at 194.

3. Multiple Compounds Can Be Used in the Claimed Method

As the issue of enablement is relevant in the cases discussed above as well as in the present case, one focal point of the analysis is "undue experimentation." In all of the above cases, there were multiple compounds identified for use in the invention and a clear sense from the specification that alternatives not identified in the specification were available. Although any new compounds might or might not be independently patentable, testing the use of any new compound in the claimed method is routine and does not require undue experimentation.

B. Since Functional Language is Permitted Where Compositions are Not at the Point of Novelty, *UC v. Eli Lilly* is Not Applicable to the Instant Claims

The Examiner notes that the pending method claims recite a method of preparing a library of compounds, and argues that without identifying the required precursor molecules that can be used to establish the library of compounds, the claimed method of producing the desired library compounds cannot be accomplished. The Examiner cites *UC v. Eli Lilly* 1997, U.S. App. LEXIS 18221 for support of this position.

In response, applicants respectfully urge reconsideration. The law relied upon by the present Examiner is misapplied to the invention at hand. This is because the claims of this invention are not directed to the compounds of the library *per se*; but, to the method of preparing a library of compounds.

According to the law, the propriety of description rejections are considered to be highly fact dependent. The Examiner is reminded of the Federal Circuit's admonition in *Vas-Cath* at page 1562 where the court quoted the CCPA in the *Driscoll* decision:

It should be readily apparent from recent decisions of this court involving the question of compliance with the description requirement of § 112 that each case must be decided on its own facts. Thus, the precedential value of cases in this area is extremely limited.

In re Driscoll, 562 F.2d 1245, 1250, 195 U.S.P.Q. 434, 438 (CCPA 1977). In *UC v. Eli Lilly*, the inventors were claiming novel *things* and their claims included *things* not in their possession, yet to be discovered and thus not described. In stark contrast, the claims of the present invention read on a novel *method* of linking old *things* (chemical components). Because the chemical components of the instant claims are not the patentable feature, the specification need not possess all possible chemical components.

The rejected claims can be viewed as analogous to a software program to correct spelling errors. In a claim directed to such software, we need not include or possess all existing and future English words to recite comparing a user entered word against a dictionary of words. Accordingly, methods of constructing compounds as described in the present invention need not describe all possible chemical components that are useful in the method.

C. As the “library of compounds,” “compound,” “synthesis template,” “scaffold functional group,” “reactive component,” “linkers,” etc., of the Instant Claims are Not at the Point of Novelty of the Present Invention, Functional Language is Permitted

The final step in this analysis is to distinguish between those fact patterns when method claims can include novel, yet to be discovered things (chemical components) and when method claims cannot claim so broadly. As discussed above, the case law is clear on this. The test is one of “inventive principle.” Where the patentable feature is the chemical component,

method claims cannot include chemical components beyond your possession; but where the patentable aspects of the claims resides outside the chemical components, broad protection is available for the chemical components themselves.

As noted above, the present invention describes a method of preparing a library of compounds where the coding step occurs simultaneously with the step of preparing the compound. Thus, each coding building block is prepared simultaneously with the corresponding scaffold building block. The present invention is drawn to a method of preparing the coding building block simultaneously with the scaffold building block, and not to the chemical moieties of the “library of compounds,” “compound,” “synthesis template,” “scaffold functional group,” “reactive component,” “linkers,” etc.

Herschler is particularly on point in the present case. In *Herschler*, the invention was a method of passing steroids through the skin using DMSO and the *Herschler* claims were appropriately not limited to known steroids. Like *Herschler*, applicants’ invention is a method claim that has broad application to a variety of different chemical compositions (polypeptides and nucleic acids vs. steroids). As in *Herschler*, the chemical components of the present invention are not the invention nor the inventive principle. The fact that both unknown and known components can be used in the instant method does not detract from the patentability of the broad method claim. This is because the nature of the components being used and being prepared do not constitute the **inventive principle**.

In the biotechnology arts, claims are often encountered that read on methods for detecting a novel protein using antibodies specific for the novel protein; methods of using a novel electrophoresis gel for separating proteins, or a method of treating a disease by administering a drug that does X. In each example, the inventive principle is described under §112; yet, the claims still read on unknown species of antibodies that bind the novel protein, undiscovered proteins to be separated and newly identified drugs that do X. This is the law of **inventive principle** being properly and logically applied to our description laws.

Had the present invention been the discovery of specific chemical compounds that are made using the method of the present invention, the Examiner’s position would be legally proper. However the invention is not about novel compositions. The point of novelty of the

present invention is the method of preparing the coding building block simultaneously with the corresponding scaffold building block, not what the specific library compounds are. Description rejections are fact dependent and the instant facts do not support a rejection based on case law where the inventions were compositions *per se*.

Applicants believe that they have addressed all the concerns raised by the Examiner relating to description. Reconsideration and withdrawal of the rejection is requested in view of the comments set forth above.

II. REJECTION UNDER 35 U.S.C. § 112, 2d

Claims 1-7, 12, 15-18, 20 and 29 have been rejected under 35 USC § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Applicants respectfully traverse the rejection in view of the comments below.

The test for indefiniteness is “whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity” (MPEP § 2173.02). This analysis does not occur in a vacuum, but rather in view of the following factors: (1) the content of the particular application disclosure; (2) the teachings of the prior art; and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. In addition, “the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope” (MPEP § 2173.02).

1. “said first compound” of claim 1

The Examiner alleges that there is insufficient antecedent basis for this limitation. Applicants respectfully disagree.

Applicants note that step (c) of claim 1 has been amended to recite “a first compound of said library of compounds.” As the recitation “a first compound” is the first recitation of “first compound”, claim 1 is not indefinite under 35 U.S.C. § 112, 2d paragraph. Accordingly, Applicants respectfully request that the Examiner withdraw this aspect of the rejection.

2. “wherein at least two coding tag precursors” of claim 1

The Examiner alleges that it is not clear as to which part of the synthesis template the coding tags are attached, leaving open whether the coding tags are attached to the “scaffold” or if the tags are attached elsewhere on the solid support. Applicants respectfully disagree.

Applicants note that claim 1 originally recited “at least two coding tag precursors ... attached to said solid support.” In order to more clearly state that the coding tag precursors are linked to the solid support, claim 1 has been amended to recite “wherein said solid support is linked to at least two coding tag precursors.” Accordingly, claim 1 is not indefinite under 35 U.S.C. § 112, 2d paragraph. Accordingly, Applicants respectfully request that the Examiner withdraw this aspect of the rejection.

3. “said compounds” of claims 2, 5 and 16

The Examiner alleges that there is insufficient antecedent basis for the limitation of “said compounds” in claims 2, 5 and 16, further stating that claim recites various compounds (such as “a library of compounds”, “synthesis template”, “functional groups”, “tag precursors”, “first reactive components”, “first compound”, etc.) Applicants respectfully disagree.

Applicants respectfully note that the only reference in independent claim 1 to “compounds” is “library of compounds.” Reference in dependent claims to “compounds” does not refer to “synthesis template”, “functional groups”, “tag precursors” or “first reactive components”, but only to “library of compounds.” As there is only one recitation of “compounds” in independent claim 1, later recitations of “compounds” in dependent claims 2, 5 and 16 find sufficient antecedent basis in claim 1. Thus, claims 2, 5 and 16 are not indefinite under 35 U.S.C. § 112, 2d paragraph for reciting “compounds.” Accordingly, Applicants respectfully request that the Examiner withdraw this aspect of the rejection.

III. REJECTION UNDER 35 U.S.C. § 102(b) OVER LEBL

Claims 1-7, 12, 15-18, 20 and 29 have been rejected under 35 USC § 102(b) as allegedly being anticipated in view of Lebl. Applicants respectfully traverse the rejections in view of the comments below.

A claim is considered to be anticipated under 35 USC § 102(b) if “the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.” In order for a claim to be anticipated by a reference, the reference must teach every element of the claim (MPEP § 2131, citing Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). As discussed in detail below, the presently claimed invention is not anticipated in view of any of the cited references as all the references fail to teach every element set forth in the claims of the instant invention.

The Examiner alleges that Lebl teaches each element of independent claim 1. Applicants respectfully traverse the rejection in view of the comments below.

Applicants note that Lebl fails to teach step (b) of amended claim 1:

contacting a first synthesis template with a first reactive component such that the first reactive component reacts with both a first scaffold functional group and a first coding functional group, wherein said first scaffold functional group reacts with said first reactive component to afford a first scaffold building block, and wherein said first coding functional group reacts with said first reactive component to afford a first coding building block

Step (b) of amended claim 1 provides that the first reactive component reacts with both the first scaffold functional group and the first coding functional group *simultaneously in the same reaction*. Thus, the first scaffold building block and the first coding building block are prepared *simultaneously in the same reaction*. Applicants respectfully submit that Lebl fails to teach preparation of the first scaffold building block and the first coding building block simultaneously in the same reaction.

In order to teach step (b) of amended claim 1, the Examiner relies on cols. 10-11 of Lebl, especially col. 10, lines 55+ and col. 11, lines 36+. Applicants respectfully note that the Examiner has overlooked a critical teaching of Lebl at col. 11, lines 10-16:

Preferably, a coding molecule is synthesized in parallel with the synthetic test compound. In this instance, before or after linking the subunit of the synthetic test compound to the support in step (ii), one or more subunits of the coding molecule, that correspond(s) to the added subunit of the synthetic test compound, is linked to the growing coding molecule

This recitation of Lebl clearly teaches that the coding step occurs either **before or after** the step linking a new subunit to the test compound. In this manner, for each step of linking a new subunit to the test compound of Lebl, the corresponding subunit is added to the coding molecule. Thus, the test compound and the corresponding coding molecule of Lebl are prepared in a *parallel* procedure, but not simultaneously. The test compound and the corresponding coding molecule of Lebl are **not** prepared *simultaneously in the same reaction*, as in the instant invention.

As Lebl teaches a method for preparing a library of compounds where the coding step occurs either **before or after** the step linking a new subunit to the test compound, Lebl fails to teach the step of the present invention where the these steps occur *simultaneously in the same reaction*. Since Lebl fails to teach an element of the instantly amended claims, Lebl does not anticipate the instantly amended claims under 35 U.S.C. § 102(b). Accordingly, Applicants respectfully request that the Examiner withdraw this aspect of the rejection.

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Amdt. dated October 31, 2007
Reply to Office Action of July 6, 2007

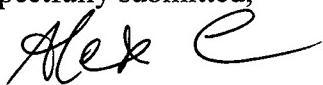
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CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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